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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D-1266]

Draft Guidance for Industry on Placing the Therapeutic Equivalence Code on Prescription Drug Labels and Labeling; Availability; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until (*insert date 60 days after date of publication in the Federal Register*), the comment period for the draft guidance for industry entitled "Placing the Therapeutic Equivalence Code on Prescription Drug Labels and Labeling" that appeared in the **Federal Register** of January 28, 1999 (64 FR 4434). FDA is taking this action in response to several requests for an extension and to allow interested parties additional time to submit comments.

DATES: Written comments may be submitted by (*insert date 60 days after date of publication in the Federal Register*). General comments on agency guidance documents are welcome at any time.

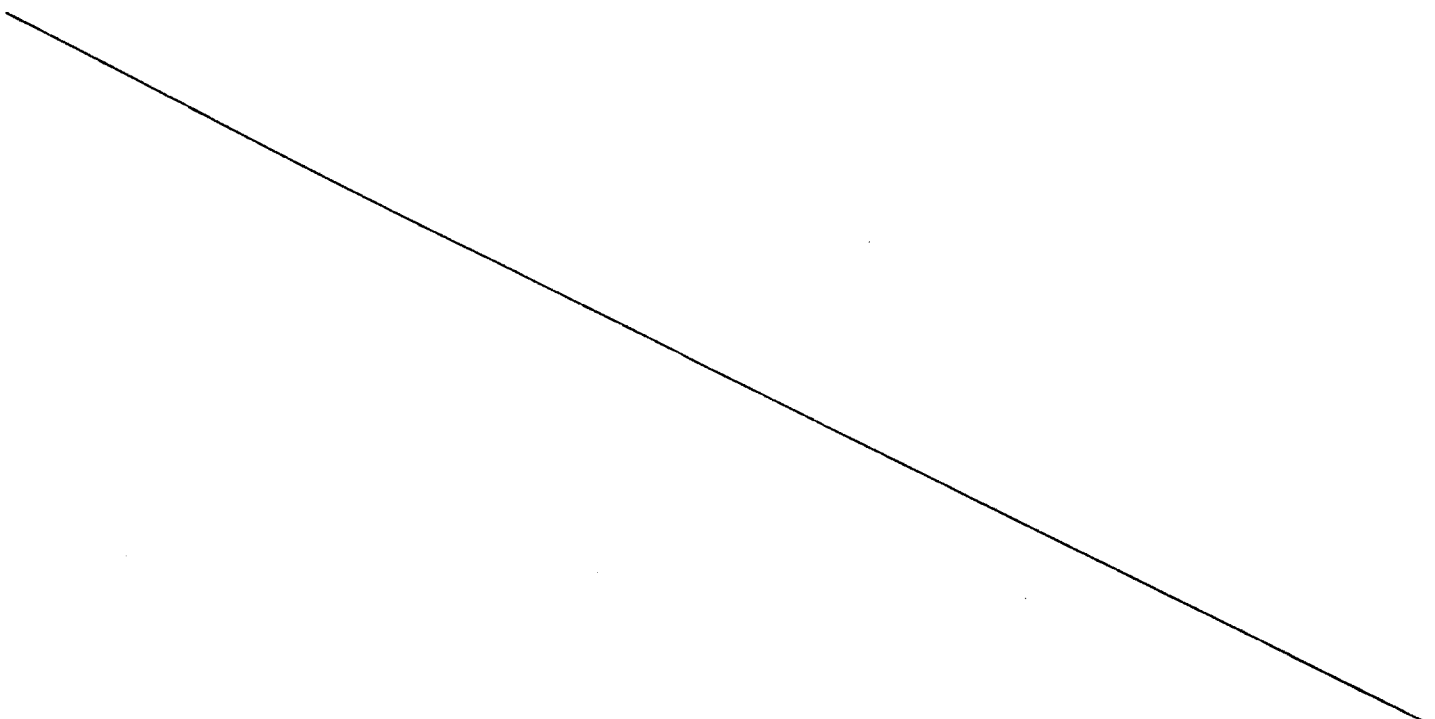
ADDRESSES: Copies of the draft guidance for industry are available on the Internet at "http://www.fda.gov/cder/guidance/index.htm". Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments are to be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jerry Phillips, Center for Drug Evaluation and Research (HFD-730), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3225.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 28, 1999, FDA published a notice announcing the availability of a draft guidance for industry entitled “Placing the Therapeutic Equivalence Code on Prescription Drug Labels and Labeling.” The draft guidance is intended to clarify for prescription drug manufacturers, relabelers, and distributors FDA’s position regarding placing the therapeutic equivalence code on approved FDA product labels and labeling. The January 28, 1999, notice invited interested persons to submit written comments on the draft guidance within 60 days.

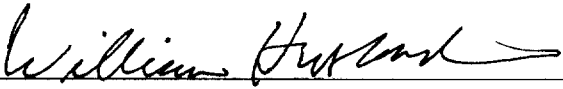
The agency has received several requests to extend the comment period on the draft guidance. The agency has decided to reopen the comment period on the draft guidance until (*insert date 60 days after date of publication in the Federal Register*), to allow the public more time to review and comment on its contents.

Interested persons may, on or before (*insert date 60 days after date of publication in the Federal Register*), submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals



may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 15, 1999



William K. Hubbard
Acting Deputy Commissioner for
Policy

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

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